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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,498	02/16/2006	Hanne Thorsoe	BJS-550-730	3495
23117 7590 03/14/2011 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
BADR, HAMID R				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,498

Applicant(s)

THORSOE ET AL.

Examiner

HAMID R. BADR

Art Unit

1781

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53, 57-73, 81-90, 92, 96, 98, 99 and 101-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53, 57-73, 81-90, 92, 96, 98-99, and 101-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' amendment filed 2/18/2011 is acknowledged.

Claims 53, 57-73, 81-90, 92, 96, 98, 99 and 101-104 are being considered on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 53, 57-73, 81-90, 92, 96, 98, 99 and 101-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 53 is indefinite for "a milk protein". Since milk comprises a variety of proteins with different characteristics whose interactions with pectins are different at various pHs, it is not clear what type of milk proteins the food material comprises. Therefore, the scope of claim 53 is not clear. If the food material is meant to simply comprise milk, which appears to be the case, the claim can be modified to recite "the food material comprises milk."

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 53, 57-73, 81-90, 92, 96, 98-99, and 101-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamime et al. (1985, Yoghurt; Science and Technology; hereinafter R1) in view Reddy et al. (WO 98/18349; on record, hereinafter R2) and Takahashi (EP 1 206 909; hereinafter R3).
3. R1 discloses processes for the production of fermented milks including yogurt, yogurt beverage, stirred yogurt, pasteurized yogurt, flavored yogurt, and yogurt beverage and drinking yogurt. The overall process is discussed on page 236 where the milk is standardized for fat content, the milk solids are fortified to 14-16% and sugar and or stabilizers are added. Given that the stabilizer is added to the intermediate before the fermentation stage, the requirement for adding the stabilizer prior to fermentation as presently claimed (claim 103) is met.
4. The yogurt base mixture is pre-warmed (50-60C), homogenized and heat treated (pasteurized) at 85C for 30 minutes, 90-95C for 5-10 minutes, or 120C for 3-5 seconds. The milk is cooled to incubation temperature. The incubation can be carried out at 42-45C (short incubation time, 2.5-3 hours, page 103, outline of the process, line 6) or at 30C (long incubation time, overnight or around 18 hours or until the desired acidity is reached, page 60, Fermentation Process). The mixture is then inoculated with starter culture (*Streptococcus thermophilus* and *Lactobacillus bulgaricus*; page 60, Fermentation Process). The yogurt product can be prepared as set yogurt or stirred yogurt. The stirred yogurt may be mixed with fruits or synthetic flavor. The set yogurt may contain fruits (page 236, Fig. 5.1).

5. R1 teaches that the yogurt may be pasteurized for producing long life yogurt.

Table 5.1 on page 237 gives multiple methods for the heat treatment of prepared yogurt.

6. R1 teaches of a process for the preparation of drinking yogurt (page 241-243).

R1 discloses that in order to overcome the problem of whey separation, it is necessary to incorporate a stabilizer into the basic mix. A typical composition of a drinking yogurt may contain 0.27% stabilizer (page 242, bottom of page, the chemical composition).

7. R1 discloses that the drinking yogurt is heat treated i.e. pasteurized in order to prolong its keeping quality. (page 242, last line).

8. R1 teaches of fortification of milk solids. Different types of milk powder can be used to fortify the yogurt milk. Skim milk powder is used most widely. The dried ingredients are incorporated into the aqueous phase which could be whole milk, skim milk or water (page 111, (b) Addition of milk powder). Other types of protein forms e.g. casein powder (isolated protein) can be added to the yogurt base. (page 18, addition of casein powder).

9. R1 discloses the type of stabilizers which can be used in yogurt. Among the stabilizers/emulsifiers pectins (High molecular weight, HE), low methoxy pectins (High molecular weight, LE), soy protein (vegetable protein) can be used (page 25-26, Table 2.9).

10. While R1 clearly teaches of using pectins (HE) and low methoxy pectins (LE) as stabilizers in the yogurt products, it is silent regarding the use of depolymerized (low molecular weight or hydrolyzed pectins) in yogurt products.

11. R2 discloses the incorporation of hydrolyzed pectin (depolymerized pectin) into milk and pasteurizing the milk containing hydrolyzed pectin. The foodstuff may be a milk beverage or beverages containing juice. The complex added to the milk consists of calcium and a hydrolyzed polysaccharide alone or together with an acid. (page 2, lines 1-10)
12. R2 gives the details of the hydrolysis of the polysaccharides including pectin. (page 2, lines 14-22)
13. The amount of complex to be added to milk is disclosed to be 0.05 to 5% based on the weight of the foodstuff. (page 3, lines 14-16)
14. R2 discloses a process in which calcium chloride and hydrolyzed pectin are mixed and added to skim milk. The milk is then homogenized and pasteurized resulting in a milk product which is stable, without sediment and of good flavor after 7 weeks of storage. (page 3, Example 1 to page 4, lines 1-4).
15. R2 also prepares a milk product containing pectin hydrolysate (depolymerized pectin), calcium and acid. The mixture is homogenized and pasteurized resulting in a stable product without sedimentation and of good flavor after 7 weeks. (Page 4, Example 2)
16. Given that the hydrolyzed pectin added to milk does not cause incompatibility, evidenced by the stable milk product after 7 weeks of storage, even after pasteurization in the presence or absence of an acid, it is clear that the problem of incompatibility of high molecular weight pectin and milk, specifically when heat treated, is solved by using hydrolyzed pectin. However, while an artificial acidification is being practiced by

R2, since the milk containing the hydrolyzed pectin is stable after pasteurization, it can be inoculated with common starter cultures and the acidification can be brought about biologically through fermentation as presently claimed. The stable milk product will remain stable even after the gradual acidification caused by fermentation.

17. R2 is silent regarding the viscosities of the various hydrolyzed pectin products as presently claimed.

18. R3 discloses stabilizers for acidic foods containing proteins. These stabilizers are pectins having low molecular weight (i.e. depolymerized pectins) and a viscosity of no more than 150 mPa.s (Abstract).

19. R3 teaches of incorporating low molecular weight pectins into acidic foods at greater than 0.4% by weight. The low molecular pectins have a viscosity of no greater than 150 mPa.s at 5% solution at 25C. [0011]. This is equivalent to 150 cP. The low molecular pectin preferably shows a viscosity of 20-90 mPa.s (20-90 cP) for a 5% solution at 25C [0021]. The upper limit for usage of the low molecular pectin is 5% [0023]

20. R3 discloses that a high methoxy pectin of at least 50% esterification (DE) is suitable when used as low molecular weight pectin. [0014].

21. R3 discloses that proteins in acidic milk beverages such as liquid yogurt, lactic acid bacteria beverages, fruit milk and the like are highly unstable at pH 3.8-5.3 [002]. The acidic foods which can take advantage of stabilizing effects of low molecular pectins are foods containing animal or vegetable proteins and include acidic protein

beverages prepared by adding citrus juices or other juices, organic acids such as citric and lactic, inorganic acids, beverages containing soybean milk etc. [0025].

22. R3 uses a pectin with a DE of 71% for the preparation of low molecular weight pectin. [0027]. It is noted that pectins are usually used in the form of powder as presently claimed. It is obvious that either High esterified pectin (HE, DE >50%) or low esterified pectin (LE, DE <50%) can be depolymerized as disclosed by R3.

23. It is also obvious that depending on the desired viscosity, texture and taste of the various fermented products, depolymerized pectin, HE depolymerized pectin, LE depolymerized pectin, regular pectins (unhydrolyzed pectin) and combinations thereof could have been used as taught by R1-R3. It is noted that optimization of process conditions and the type of depolymerized pectins used in various product will depend on the product, the pH of the product, concentration of calcium and magnesium ions, desired texture, taste and viscosity of the products. Therefore, using depolymerized pectins in yogurt products, as disclosed by R3, was known in the art for the very purpose of stabilizing milk proteins. Manipulation of the yogurt formulations for pH, calcium ion concentration, viscosity etc. to prepare products as presently claimed, would be well within the skill of the art.

24. It is noted that amidated pectins can be prepared by reaction of ammonia and pectins. Therefore, depending on the process by which the pectin is de-esterified, amidated pectins may be resulted when ammonia is used as the de-esterification agent. This means that a regular high molecular weight pectin may have amide groups (reaction of galacturonic acid and ammonia). Depolymerizing such a pectin will yield

amidated depolymerized (low-ester, low molecular weight) pectins which can be used as presently claimed. Amidation together with depolymerization process will further improve the solubility of pectins at lower temperatures involved in the storage of yogurt products.

25. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 and incorporate hydrolyzed pectins as stabilizers in the base mix, pasteurize the mix, and cool the base mixture as disclosed by R2, inoculate and ferment the base mixture to acidify the mixture as disclosed by R1. The preparation of various depolymerized pectins can be carried out as taught by R3. One would use the depolymerized pectins as stabilizers in fermented milk products to overcome the incompatibility problems caused by high molecular weight pectins at milk pH around 7.0. Absent any evidence to contrary and based on the teachings of the combined references, there would be a reasonable expectation of success in preparing a fermented milk product containing depolymerized pectins which have been incorporated in milk before the fermentation of milk.

Response to Arguments

Applicants arguments have been reviewed. However, these arguments are not persuasive for the following reasons.

1. Applicants argue that R1 does not disclose the use of depolymerized pectin as a stabilizer, nor does R1 disclose the addition of depolymerized pectin to milk.

a. The examiner acknowledges that R1 does not disclose depolymerized pectins. However, the rejection is an obviousness type rejection, the teachings of all involved references are to be considered.

2. Applicants argue that R2 discloses the fortification of food stuffs with calcium, using depolymerized pectin without causing a high viscosity.

a. Therefore, it can be said that R2 teaches of how to solve the viscosity problem using depolymerized pectin. R2 is being used in an obviousness type rejection, involving other references. It cannot be judged on its own.

3. Applicants argue that it would have not been obvious for an ordinary skill to have incorporated 0.3-3.0 wt. % of a depolymerized pectin such as those described in R2 and R3.

a. R3 clearly teaches of incorporating depolymerized pectins at above 0.4 wt. % for creating viscosity effects. R3 also discloses the viscosities associated with such depolymerized pectins. Therefore, optimizing the concentration of depolymerized pectins, in fermented products, for higher or lower viscosities would have been motivated and obvious to the ordinary skill in the art.

4. Applicants argue that the Examiner has used impermissible hindsight.

a. The Examiner disagrees. The motivation for using depolymerized pectins is given in the references cited in the rejections, for exactly controlling the viscosity of the fermented product. However, the rejection is an obviousness type rejection which is logically based on hindsight as long as the information comes from the cited references. The teachings of R1-R3 make the presently claimed invention obvious.

5. Applicants argue that neither R1 nor R2 provide the ordinary skill in the art with any information on the effect of these calcium complexes may have on the starter culture.

a. All products disclosed by R1-R3 comprise calcium. Therefore, adding calcium to something already containing calcium would not cause any problem as long as it is stabilized by compounds such as depolymerized pectin, which is taught by R2. R2 clearly teaches of using depolymerized pectins as stabilizing agent. Therefore, R2 is solving the problem with which the applicants were concerned.

6. Applicants argue that R2 does not teach the use of hydrolyzed pectin alone as a stabilizer of milk proteins.

a. R2 clearly teaches that hydrolyzed pectin (on its own) is the stabilizing agent. The complex, of course, provides calcium for fortification, but what stabilized the system is the depolymerized pectin.

7. Applicants argue that R3 is concerned with lowering the viscosity of pre-acidified milk while ensuring stability.

a. As long as R3 teaches of using depolymerized pectins in the stability of the system under acidic conditions, its application in manufacturing yogurt would have been motivated and obvious to those of ordinary skill in the art.

8. Applicants argue that there is no teachings in R3 that depolymerized pectins would be able to stabilize non-acidified milk.

a. In the art of fermented milk products, including yogurt, the stability (lack of syneresis or whey separation) is sought in the final product which is always acidified. Therefore, the stability of non-acidified milk as portrayed by applicants is not relevant.

9. Applicants argue that the addition of pectins prior to fermentation induces phase separation, which in the present case is undesirable as it adversely affects the characteristic yogurt structure.

a. R1 clearly discloses that the yogurt pre-mix, including the stabilizer, is pasteurized and then fermented. Therefore, addition of the stabilizers, including pectins per R1, would be desirable.

10. Applicants argue that R3 teaches of adding the depolymerized pectin after the fermentation, there is not teaching or suggestion that it can be added before the fermentation.

a. Addition of pectins before the fermentation step is disclosed by R1. R3 does not have to teach the same concept.

11. Applicants argue that the results in the Table on page 43 show, for example, that yogurt samples containing 0.3 weight % of depolymerized pectins and above exhibits increased viscosity, enhanced sensory thickness and creamy perception. Also, high dosages of depolymerized pectin can be dry-blended, hydrated and pasteurized before fermentation without creating grittiness.

a. Inclusion of depolymerized pectins in fermented milks is disclosed by R2 and R3. The results that applicants are referring to, are all expected when the depolymerized pectins are included in yogurt formulations.

12. Applicants argue that; manipulation of viscosity, would not have been routine for the ordinary skilled person.

a. According to teachings of R2 and R3, depolymerized pectins would have been obviously affected viscosity. The viscosity being a function of molecular weight and concentration would have been obvious to ordinary skill in the art. Once this fact is known, increasing or decreasing the concentrations to manipulate viscosity would have been motivated and obvious to an ordinary skill in the art.

13. Applicants argue that in fact, R3 teaches that the addition of low molecular size pectin results in a lower viscosity than traditional pectins, therefore, the ordinary skill would have had no reasonable expectation that incorporating depolymerized pectin in the specific amount presently claimed would lead to dairy products with improved quality.

a. This teaching is fundamental in optimizing the concentration of the depolymerized pectins. It is true that at the same concentration, the viscosity of traditional pectin solutions is higher than the viscosity of depolymerized pectins, because viscosity is a function of molecular weight of macromolecules such as pectins. No inventive step is recognized in the presently claimed invention.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr
Examiner
Art Unit 1781

/Keith D. Hendricks/
Supervisory Patent Examiner, Art Unit 1781